PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P51216	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/00099	International filing date *(day/month/year)* 03 January 2003 (03.01.2003)	Priority date *(day/month/year)* 03 January 2002 (03.01.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 9/20 and US Cl.: 424/464, 486, 493, 494		
Applicant SMITHKLINE BEECHAM CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24 July 2003 (24.07.2003)	18 November 2003 (18.11.2003)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer Lakshmi Channavajjala Telephone No. 703-308-1235

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
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I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-62 as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the claims:
pages 63-73 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the drawings:
pages 1-3 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 20

because:

☐ the said international application, or the said claim Nos. ____ relate to the following subject matter which does not require international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. ____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. ____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 20

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	1-19 and 21-50	YES
	Claims	NONE	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-21 and 21-50	NO
Industrial Applicability (IA)	Claims	1-21 and 21-50	YES
	Claims	NONE	NO

2. CITATIONS AND EXPLANATIONS
Please See Continuation Sheet

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

V. 2. Citations and Explanations:

Claims 1-19 and 21-50 lack an inventive step under PCT Article 33(3) as being obvious over Breitenbach et al (Breitenbach) in view of Jane et al (Jane) and Kiczek et al (Kiczek).

Breitenbch teaches solid foamed active material composition comprising polymers and active agents, prepared by a process of melt extrusion and foamed. The Breitenbach teaches that employing thermoplastic polymers in the composition reduces the storage stability of the drug, which is overcome by the foamed active ingredient. Breitenbach teaches employing various drug, polymers, starches, plasticizers, bulking agents (such as xylitol) etc (col. 1-3). Breitenbach teaches melt extrusion process in preparing the dosage forms and suggests heating, applying pressure before melt extrusion, injecting an inert gas and reducing the pressure and cooling so as to form the foamed dosage form. Breitenbach does not teach cellular or micro cellular foamed dosage form.

Jane teaches soy-protein based thermosetting polymers composition prepared by mixing soy protein, foaming agent, plasticizing agent aqueous medium in low amounts (lines bridging columns 1 and 2). The composition is mixed and molded into an article by compression molding or extruded at 80 to 100 degrees C to produce pellets. Jane teaches foaming agents (col. 3, lines 6-33) and plasticizers, which include the claimed polyols such as mannitol, maltritol etc (col. 3, lines 51-56), additives, fillers and other extender polymers (col. 4). Jane also suggests molding the composition to provide high proportion of closed cells and thus low level of thermoconductivity. Further, Jane teaches the cells have diameter of 10-200 microns and thus read on the micro cellular material of the instant claims. Jane teaches the composition for packaging drugs but not for oral administration.

Kiczek teaches a process of extruding thermoplastic polymer materials at low-pressure inert gases as foaming agents that include the same sequence or steps as claimed. Accordingly, preparing closed cellular or micro cellular foamed materials (as suggested by Jane) using the method or process of Kiczek in preparing the oral dosage forms of Breitenbach would not involve inventive step because Kiczek teaches employing non-hazardous, inexpensive foaming agents in the process of preparing foaming agents and Jane suggests that the foamed
Materials having cell diameter of 10-200 microns impart low thermal conductivity, and high degree of thermo insulation and thus provide shelf stability, desired by Breitenbach.

Claims 1-19 and 21-50 meet the criteria set out in PCT Article 33(2) because employing molded micro cellular non-thermosetting polymeric materials for preparing oral dosage compositions is novel. The prior art molded micro cellular non-thermosetting polymeric materials for forming the packaging materials for food and drugs but not oral dosage forms.

Claims 1-19 and 21-50 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

---------- NEW CITATIONS ----------

P { US 5,710,190 A (JANE et al.) 20 January 1998. See entire document.
US 6,150,424 A (BREITENBACH et al.) 21 November 2000. See entire document.

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